REMARKS

Claims 1-3, 5-7 and 9-12 are pending in this application. No amendment is made in this Response. It is believed that this Response is fully responsive to the Office Action dated **December 17, 2010**.

Claims 1-3, 5-7, and 10-12 are rejected under 35 U.S.C. §103(a) as being unpatentable over Luhadiya et al. (US 6,811,800 B2) as evidenced by Mallangi et al. (US 6,039,986). (Office action p. 2)

The rejection of claims 1-3, 5-7 and 10-12 is respectfully traversed and reconsideration is requested.

Summary of the rejection as stated

The Examiner cites Luhadiya for disclosing a calcium fortified beverage, and in particular, cites the reference for disclosing a milk composition with up to 3100 ppm additional soluble calcium, 0.002-2.5% added stabilizer and 0-0.5% of a chelating agent (column 4, lines 60-67); or up to 2500 ppm additional soluble calcium, 0.002-1% added stabilizer, and 0-0.35% chelating agent (column 5, lines 1-6); or up to 2200 ppm additional soluble calcium, 0.005%-0.5% added stabilizer, and 0-0.15% chelating agent (column 5, lines 6-12). The Examiner discusses related disclosures in other parts of the reference. The Examiner cites Luhadiya for disclosing that stabilizer can be gum arabic (column 5, line 61, through column 6, line 8), and that the chelating agent can an organic acid or salt, and can be sodium citrate (column 6, lines 17-33). The Examiner also states that the additive calcium can be calcium carbonate (column 8, lines 40-44) and that this meets the limitation of inorganic compound (A) in claim 1. The

Examiner implies that the ranges of concentrations of stabilizer and chelating agent overlap the ranges of gum arabic (B) and chelating agent (C) in the claims.

The Examiner states at page 4, line 10, of the Office action, that it would have been obvious "for the calcium enriched milk taught by Luhadiya to contain as low as an amount as possible, including as low as 0%, calcium ions, in order to ensure that there were no free calcium ions to destabilize the milk proteins ....; to do so would be obvious to one of skill in the art as it was well known in the art, as evidenced by Mallangi, for protein destabilization, e.g. coagulation and precipitation, in materials, such as milk, to be mainly attributed to free calcium ions in the system (column 1 lines 26-33)."

Arguments

Regarding Luhadiya et al.

The Luhadiya et al. reference discloses calcium fortified protein-containing beverages that contain high levels of soluble calcium (Abstract).

The compositions of Examples 1 and 2 of the reference are tabulated below with calculated parts by weight:

Example 1:

Ingredients	% w/w	Parts by weight
Calcium hydroxide	3.97	100
Citric acid	3.66	} 186
Malic acid	3.75	
Water	88.62	
	100.00	

Example 2:

Ingredients	% w/w	Parts by weight
Calcium hydroxide	7.94	100
Citric acid	7.32	186
Malic acid	7.50	
Water	77.24	
	100.00	

Upon comparison of Luhadiya to the present invention, the following differences are seen:

(a) Luhadiya attains stabilization by employing soluble calcium, which is obtained by dissolving a calcium compound in a chelating agent, while the present invention attains the stabilization by adding gum arabic and a chelating agent to a hardly soluble inorganic compound.

Although the present invention uses a hardly soluble inorganic compound, it is dissolved in a small amount. For example, when calcium carbonate is used, a small amount of the calcium carbonate is dissolved and exists as calcium ion. Accordingly, in the present invention, the chelating agent acts on this calcium ion to adjust the calcium ion concentration M to the claimed range $0 \leq M < 10$ to make the food additive composition stable.

(b) The present invention uses the chelating agent in an amount of 0.05 to 5 parts by weight to 100 parts by weight of the inorganic compound, as presently claimed by claims 1 and 2.

In the present specification, the food additive compositions of Comparative Examples 2 and 8 (summarized in Table 2 on page 37) add 6 parts by weight of the chelating agent exceeding

the upper limit of 5 parts by weight, and are inferior in flavor of the calcium-enriched whiteners, as apparent from Comparative Examples 22 and 28 in Table 7 (page 47).

In contrast, in Luhadiya, concentrated soluble calcium solutions, which correspond with the food additive composition of the present invention, of Examples 1 and 2 use the chelating agent (citric acid and malic acid) in an amount of 186 parts by weight, respectively, to 100 parts by weight of calcium hydroxide,

As stated above, Luhadiya uses the chelating agent in much greater amount than that of the present invention and with such greater amount of the chelating agent, that the object of the present invention cannot be attained, as shown by Comparative Examples 2, 8 and 22, 28.

Meanwhile, Luhadiya discloses, for example, at column 8, lines 59-61, the addition amount of a chelating agent "from 0.01 weight % to about 0.6 weight %". However, care must be taken this addition amount is not for the concentrated soluble calcium solution which corresponds with the food additive composition of the present invention, but for a calcium fortified mammal's milk (See col. 8, lines 46-47).

In the meantime, the amounts of a chelating agent pointed out by the Examiner at pages 2-3 and 6 of the Office Action are all directed to those in foods such as calcium fortified mammals milk and thus groundless, not to those in the food additive composition of the present invention.

Regarding Mallangi et al.

Mallangi et al. discloses a fortified foodstuff comprising a fortifying amount of a balanced blend of calcium lactate and calcium carbonate stabilized with a source of gluconic acid (Abstract).

In Examples 1-4 of the reference, calcium fortified skim or chocolate milks are prepared, in which:

Ingredients	(g)	Parts by weight
Calcium lactate pentahydrate	126.5	100
Micronized calcium carbonate	216.7	
Potassium citrate	110	32

Upon comparison of Mallangi to the present invention, the following differences are seen:

(a) Mallangi uses potassium citrate in the examples, but the purpose of using the potassium citrate is nowhere described. Moreover, adjusting the calcium ion concentration M to the specific range of $0 \leq M < 10$ is not disclosed in the reference.

(b) Mallangi uses potassium citrate in an amount of 32 parts by weight to 100 parts by weight of calcium compounds, which **exceeds** the upper limit of 5 parts by weight in the food additive composition of the present invention, as in the case of Luhadiya.

In the meantime, attention is drawn to the point that the calcium fortified skim or chocolate milks correspond with a food composition such as calcium or magnesium-enriched whiteners containing a food additive composition of the present invention in which 0.01 to 5 parts by weight of a chelating agent is (are) contained. That is, the food composition added with the additive composition of the present invention contain the chelating agent in amounts of much smaller than 0.01 to 5 parts by weight contained in the food additive composition.

Regarding the combination of references

As noted above, Luhadiya does not disclose the limitation of $0 \leq M \leq 10$ required by claims 1 and 2. In fact, the purpose of Luhadiya is to obtain high levels of soluble calcium (abstract), and the purpose of Luhadiya is to not to obtain a food additive composition, as in the present invention. There is no suggestion in Luhadiya for the limitations of the present invention.

Mallangi also does not disclose the limitation of $0 \leq M \leq 10$, and in fact, discloses use of potassium citrate at levels exceeding the level required by the present claims.

The Luhadiya and Mallangi references generally correspond to the Comparative Examples of the present specification, since the amount of a chelating agent greatly exceeds the upper limit of the present invention.

No combination of Luhadiya and Mallangi can produce the limitations of the present claims, and claims 1-3, 5-7, and 10-12 are not obvious over Luhadiya et al. (US 6,811,800 B2) and Mallangi et al. (US 6,039,986), taken separately or in combination.

Claim 9 is rejected under 35 U.S.C. §103(a) as being unpatentable over Luhadiya et al. (US 6,811,800 B2) as evidenced by Mallangi et al. (US 6,039,986), further in view of Hojo et al. (US 6,254,905 B1). (Office action p. 5)

Alternatively, claims 1-3, 5-7, and 9-11 are rejected under 35 U.S.C. §103(a) as being unpatentable over Luhadiya et al. (US 6,811,800 B2) as evidenced by Mallangi et al. (US 6,039,986), in view of Hojo et al. (US 6,254,905 B1). (Office action p. 6)

These rejections are respectfully traversed and reconsideration is requested.

Summary of the rejection as stated

The Examiner again cites Luhadiya for disclosing a calcium fortified protein containing beverage, and states that Luhadiya is silent regarding the particle diameter of the inorganic compound. The Examiner cites Hojo et al. for disclosing a food additive composition containing an organic compound calcium carbonate, and cites Hojo at column 9, lines 7-23, for disclosing the particle size limitations of claim 9. The Examiner states that it would have been obvious for the inorganic calcium carbonate in Luhadiya to have the particle diameter limitation of Hojo "for the purpose of fairly long storage stability as taught by Hojo."

The combination of the Luhadiya and Hojo references is also discussed at the bottom of page 8 of the Office action, where the Examiner states: "the teachings of Luhadiya clearly encompass the claimed stabilizer and stabilizer/additive compositions, and the selection of a known stabilizer/additive for optimization of stability would have been obvious and routine determination to one of ordinary skill in the art."

Arguments

Applicant has argued above that no combination of Luhadiya and Mallangi can provide the limitations of base claim 1 and 2. Further combination with Hojo also cannot provide these limitations.

Hojo is perfectly silent with regard to stabilizing with a chelating agent. Without using a chelating agent, the food additive composition suitable for foods such as a whitener and a potion which require a long relishing period cannot be provided (See Experiments 1 to 4 of the Declaration dated August 10, 2010, filed with the Response of August 12, 2010).

Hojo discloses using ferrous gluconate but it is merely mentioned as a fortified mineral, not as a chelating agent. Gluconates are not included in the Markush group of chelating agents (C) of the present claims.

Further, Hojo discloses that the calcium ion concentration M is in the range given by: $10 < M \leq 500$ (column 3, lines 51-64). That is, the value of M is greater than 10, which is above the maximum value in the present claims. Moreover, the reference specifically states that if M is less than 10 mg/l, the surface stability of the calcium agent is unstable and the calcium agent becomes easy to aggregate again.

Therefore, as Applicant has previously argued, Hojo explicitly **excludes** the claimed calcium ion concentration " $0 \leq M < 10$" and **teaches away** from this limitation.

Hojo et al. is analogous to the Comparative Examples in the present specification since a chelating agent is not required and since the claimed range of the calcium ion concentration is explicitly excluded.

Therefore, no combination of Luhadiya et al., Mallangi et al. and Hojo et al. can provide the limitations of base claims 1 and 2, and the pending claims are not obvious over these references, taken separately or in combination.

Claims 1-3, 5-7, and 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hojo et al (US 6,254,905 B1) in view of the combination of Koumarianos (US 6,488,957) and Grossman (About.com, "Facts About Iron" pp. 1-5 http://ibdcrohns.about.com/cs/nutrition/a/fdairon.html) and Klahorst ("Calcium, An

Important Nutrient" pp. 1-5 http://www.ifanca.og/newsletter/2001_05.htm) and Fennema (Food Chemistry, 2nd Edition, pages 778 and 779). (Office action p. 10)

The rejection of claims 1-3, 5-7 and 9-12 is respectfully traversed and reconsideration is requested.

Summary of the rejection as stated

The Examiner cites Hojo '905 for teaching a food additive composition containing 100 parts by weight of calcium carbonate, gum Arabic and an additive include sucrose fatty acid esters having a hydrophilic-lipophilic balance of not less than 8. The Examiner states that the food additive may contain ferrous gluconate or sodium iron citrate (column 11, lines 4-8), which the Examiner states are gluconate or citrate chelating agents as claimed.

The Examiner states that Hojo is silent to the amount of the ferrous gluconate or sodium iron citrate, and cites Koumarianos for teaching a food additive composition containing minerals including iron as determined by the recommended daily dosage. Grossman is cited for teaching that the recommended daily amount of iron is 8-11 mg/day for males and 8-18 mg/day for females. Klahorst is cited for disclosing that the recommended daily amount of calcium is 1000-1300 mg/day.

Fennema is cited for disclosing that the problem of metal ion stability is addressed by the use of chelating agents, including citric acid and its derivatives, which react with metal ions to form stable complexes in food.

The Examiner states that it would have been obvious "to include an amount of the ferrous gluconate and/or sodium iron citrate and thus an amount of chelating agent in the additive composition depending on the recommended daily amounts of iron and the amount of iron

desired in the final composition as taught by Koumarianos. ..." The Examiner concludes that adding the recommended amounts in the form of ferrous gluconate and/or sodium citrate would yield a composition comprising 0.6-1.8 parts of ferrous gluconate and/or sodium ion citrate.

The Examiner also discusses "requirement (a)" at the bottom of page 12 of the Office action, stating that Hojo teaches that the calcium ion concentration is balanced for stability, and that the calcium ion concentration is 10-500. The Examiner states that it would have been obvious "to decrease the calcium ion concentration at or below 10 if at levels at and below 10 were stable, in order to ensure that protein destruction and gelling of the food composition was prevented ...." (page 13, lines 2 and ff.)

Arguments

As discussed above, primary reference Hojo is perfectly silent with regard to stabilizing with a chelating agent, and does not disclose the chelating agents (C) of the present claims.

Further, as discussed above, Hojo explicitly discloses that the calcium ion concentration M is in the range given by: $10 < M \leq 500$ (column 3, lines 51-64). That is, the value of M is greater than 10, which is above the maximum value in the present claims. Therefore, as Applicant has previously argued, Hojo explicitly **excludes** the claimed calcium ion concentration " $0 \leq M < 10$" and teaches away from this limitation.

Fennema teaches that chelating agents play a significant role in food stabilization through reactions with metallic and alkaline earth ions to form complexes.

However, Fennema is completely silent with regard to the adjustment of the calcium ion concentration M to the specific range of $0 \leq M < 10$ as well as to the combined use with gum arabic.

In the present invention, when the calcium ion concentration exceeds the upper limit of less than 10 mg/1, the additive composition excellent in dispersibility and the food composition excellent in storage stability are not obtained (See Declaration dated August 10, 2010).

Grossman and Klahorst merely show daily amounts of iron and calcium as nutritional minerals.

Koumarianos does no more than teach a food additive composition in all-in-one powder composition containing multiple vitamins, calcium citrate, minerals, herbs, beans, peas, corn, grains, flakes, berries, and cloves (Abstract).

Koumarionos uses calcium citrate as a source of calcium to be added to enhance a nutritional value, not as a chelating agent. Since the invention of Hojo et al. already has calcium, there is no motivation based on Koumarianos to add calcium citrate to Hojo.

The pending claims are therefore not obvious over Hojo et al., Koumarianos, Grossman, Klahorst and Fennema, taken separately or in combination.

Claims 1-3, 5-7, and 9-12 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, 10, and 11 of U.S. Patent No. 6,254,905 B1 ('905). (Office action p. 14)

The obviousness-type double patenting rejection is respectfully traversed and reconsideration is requested.

As Applicant has argued above, Hojo '905 discloses using ferrous gluconate but it is merely mentioned as a fortified mineral, not as a chelating agent. Gluconates are not included in the Markush group of chelating agents (C) of the present claims.

Further, Hojo discloses that the calcium ion concentration M is in the range given by: $10 < M \leq 500$ (column 3, lines 51-64). That is, the value of M is greater than 10, which is above the maximum value in the present claims. Moreover, the reference specifically states that if and that if M is less than 10 mg/l, the surface stability of the calcium agent is unstable and the calcium agent becomes easy to aggregate again.

Therefore, as Applicant has previously argued, Hojo explicitly **excludes** the claimed calcium ion concentration " $0 \leq M < 10$" and **teaches away** from this limitation. The pending claims are not obvious over the claims of Hojo '905.

If, for any reason, it is felt that this application is not now in condition for allowance, the Examiner is requested to contact the applicants' undersigned agent at the telephone number indicated below to arrange for an interview to expedite the disposition of this case.

In the event that this paper is not timely filed, the applicants respectfully petition for an appropriate extension of time. Please charge any fees for such an extension of time and any other fees which may be due with respect to this paper, to Deposit Account No. 01-2340.

Respectfully submitted,
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